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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/669,490 | 09/24/2003 | Gilbert R. Gonzales | GONZ-07 | 3979 |

26875 7590 09/19/2007
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| EXAMINER |
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WEBMAN, EDWARD J

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| ART UNIT | PAPER NUMBER |
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1616

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09/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/669,490

Applicant(s)

GONZALES ET AL.

Examiner

Edward J. Webman

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-22 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 23-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

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The declaration of Drs. Gonzales and Manfredi, filed 7/9/07 has been considered but is not deemed to overcome the rejection under 35 USC 103 over Ackman in view of Zhang et al for the reasons explained below.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ackman et al in view of Zhang et al.

Ackman et al teach compositions for improving sleep (title). Methadone, an opioid, is disclosed (column 4 line 32). Lollipops are specified (column 10 line 30).

Zhang et al teach a transmucosal drug dosage form with improved oral mucosal delivery of a pharmaceutical agent (abstract). Lollipops are disclosed (claim 24). Dextrose is specified (claim 20). Phosphate buffer is disclosed (column 11 lines 27-28). Opioid agonists are disclosed (column 9 lines 39-42). 0.05-5 mg dosages are specified (column 9 Table 1).

It would have been obvious to one of ordinary skill to use the Zhang et al vehicle to deliver the Ackman et al composition to achieve the beneficial effect of improved oral mucosal delivery. As to the claimed pH, Zhang et al disclose the same buffer as claimed. An optimum suitable pH range can be established by routine experimentation, absent a showing of criticality or unexpected results.

Applicants and the declaration argue that Ackman et al is a sedative composition, explicitly so according to applicants' remarks. However, applicants' evidence for that characterization is column 4 lines 19-32, which recited sedatives as only one class of established drugs for sleep disorders, specifically sedative antidepressants. However, methadone is in the class of opioids recited by the reference rather than the class of sedative antidepressants recited therein. Applicants and the declaration state that methadone has never been approved for sleep disorders. However, US 5,919,781 to Baker et al teaches that withdrawal syndrome occurring in opiate addicts, which includes sleep disturbances, is avoided by increasing doses of methadone as the opiate is withdrawn (column 1 lines 22-34). Applicants and the declaration further argue that one of ordinary skill would not use methadone in the composition of Zhang et al because methadone is a different class of drug with different characteristics than those recited in Zhang et al. However, the obvious composition uses the vehicle of Zhang et al to deliver the drug composition of Ackman et al for improved mucosal delivery of an opioid. That is, the obvious combination uses the vehicle of Zhang et al, rather than the particular active agents recited therein. As to the now claimed acute pain, the motivation to combine need not be applicants' motivation to invent. In re Dillon 16 USPQ2d 1897 (Fed. Cir. 1990).

Claims 1-4, 6-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Nowhere in the specification do applicants disclose the adjective "nonsedative". None of the citations in applicants' remarks contain the term. At best, applicants disclose treating a sedative effect (page 10 lines 6-7 and page 20 lines 20-21).

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J, Richter, can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


EDWARD J. WEBMAN
PATENT EXAMINER
GROUP 1500